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ABC News - Round Three: The Vaccine Machine  
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The Vaccine Machine  
Is It a Follow-the-Money Operation?

Some people question whether experts who are involved with vaccine advocacy groups that are partially funded by drug companies should also serve on government vaccine policy committees.  
<http://www.abcnews.go.com/sections/living/SecondOpinion/secondopinion.html>

By Nicholas Regush ABCNEWS.com  
Oh, what a tangled web! Now that Congress is sifting through the issues surrounding vaccine safety, the politicians might want to determine whether the vaccine policy experts they and the government health bureaucracy rely on are too one-dimensional in their thinking, and, in some cases, much too close to industry for comfort.

Lately, there has been a swell of complaints from groups and individuals about vaccine side effects and the lack of long-term scientific studies and safety data on vaccines. And, at a time when there are about 200 vaccines in the pipeline, concern is mounting that high-profile vaccine advocates and the lobbies they represent have an inordinate influence on the setting of government vaccine policy. These days, it's obvious to everyone except Rip Van Winkle that the pharmaceutical industry funds a wide range of medical ventures - everything from symposia to scientific studies to hospital research institutes. So it's common that physicians who are "players" will have some form of relationship with industry. For my taste, this union has gotten way out of whack, but for the sake of argument, let's regard it as the standard medical bedrock of our times.

#### Planetary Alignment Problem

These ties that bind must be looked at more closely, however, when the players are on committees established to help government set health policy. In the vaccine arena, two of the key groups offering recommendations are the Advisory Committee on Immunization Practices (ACIP), overseen by the CDC, and the so-called Red Book Committee of the American Academy of Pediatrics. (The FDA, which evaluates the safety and efficacy of vaccines, has its own scientific advisory panel.)

Medical advisory committees usually have mechanisms to disqualify members from voting on a product when they have a potential conflict of interest. Let's allow that these mechanisms work for specific vaccine evaluation. Those working on a vaccine bow out when that vaccine is up for discussion and vote. So everything is just fine, right?

Does the Earth spin around Jupiter?

Dr. Samuel Katz of Duke University has made a great contribution to vaccination efforts and the development of new vaccines. This week, I asked him whether he is so much an advocate for vaccines (for example, hepatitis B) that he can any longer see the forest for the trees when it comes to safety issues.

Loyal, But Objective?

Katz has served as chair of both the ACIP and the Red Book committees. He co-chairs a group called the Vaccine Initiative, which is an information and advocacy group that benefited from start-up funds from at least six vaccine manufacturers. He is listed as an advisory board member to the Immunization Action Coalition (which includes the Coalition for Hepatitis B), an advocacy group that receives funding from several vaccine makers, including SmithKline Beecham, Merck and Wyeth-Lederle. Katz, soft-spoken and friendly, said he is sensitive to the issue of the appearance of conflict of interest and that he is determined to be objective when it comes to his involvement with any vaccine recommendations. Katz feels strongly that his colleagues take the same cautious approach when it comes to vaccines. He also allows that "there is much we don't know about vaccines, and a lot of research must be done."

Here is a brief take from Katz's presentation on May 18 to a congressional committee looking into vaccine safety: "As a parent, grandparent, and physician, I feel great sympathy for the people who testified on the first panel. I wish we could find the true causes for serious, complicated and often vexing medical conditions such as multiple sclerosis and autism. But the fact is, there are no scientifically sound studies that demonstrate current immunization recommendations are a cause of autism, diabetes, asthma, inflammatory bowel diseases, SIDS, multiple sclerosis or any number of acute or chronic illnesses." I reminded Katz of this statement and the fact that not having evidence for a link between vaccines and illness doesn't mean there isn't a link; rather, in this case, it means not having enough research. He answered that there is enough research to at least conclude that most vaccines are not likely to be related to disease.

Show Me the Data

We didn't get a chance to get into the details of his claim because he had a meeting. But since it's a claim that I reject as mysterious, given the paucity of appropriate science on the potential link between vaccines to disease, I am issuing Katz the following challenge: Send me abstracts of the molecular studies that you deem sufficient to nullify

concern about complex reactions to vaccines. In other words, show me the compelling biological science upon which your views rest.

I am issuing the same challenge to Dr. Bruce Gellin, staff director for the Vaccine Initiative, which Katz chairs, and whose aim is to "serve as a source of comprehensive information on vaccination and vaccination-related issues for parents, health-care professionals and the media." Scrutinizing the group's Web site, I found strong advocacy for vaccines and not much else, although Gellin emphasized on the phone that much needs to be learned about vaccines.

In one item on the Vaccine Initiative Web site, I read that Katz and his co-chairman, Dr. Louis Sullivan, formerly head of the federal health department, are informing doctors that some issues are brewing about vaccines. "These events can be opportunities to reinforce the tremendous value of immunization to the individual and society while assuring that safety concerns are being appropriately investigated and addressed," they write, pointing out that materials to convey this message to the media are available from the Vaccine Initiative. How remarkably instructive. (Gellin informed me this week that his group no longer accepts funding from manufacturers because money from a major foundation made it unnecessary. "We always felt sensitive about our start-up funding," he said. Gee, isn't that terrific, I thought.)

#### Loose Ends

One vaccine advocate I didn't reach this week - at his office or by e-mail - is Dr. Neal Halsey of Johns Hopkins University. Like Katz, he is a vaccine pioneer and served on ACIP and the Red Book committees. He, too, is an advisor to the Immunization Action Coalition and the Hepatitis B Coalition. Halsey is also director of the Institute for Vaccine Safety, which he founded at Johns Hopkins to provide a forum on vaccine safety, among other things. According to a Johns Hopkins' spokesperson, the institute receives funds from Merck, SmithKline Beecham, North American Vaccines, Connaught/Pasteur Merrieux and Wyeth-Lederle.

Maybe when Halsey makes it back to his office, he can also send me scientific abstracts that will nullify concerns about long-term effects of vaccines on the immune system. Maybe his institute can investigate why there is such poor data on the subject. What do I make of all this? I don't think it's very pretty. The scene has more to do with politics than vaccine science. Unfortunately, the quality of human life is at stake; somehow, we had better get beyond this folly.

Nicholas Regush produces medical features for ABCNEWS. In his weekly column, published Wednesdays, he looks at medical trouble spots, heralds innovative achievements and analyzes health trends that may greatly influence our lives. His latest book is *The Breaking Point: Understanding Your Potential for Violence*.